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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/615,636

07/10/2003

Jay A. Warren

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12/29/2008

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EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

12/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/615,636	Applicant(s) WARREN, JAY A.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 39-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 9, 2008 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-23 and 39-46 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 7 still stands as rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the "QRS complex", however claim 7 recites "a T-wave". It is unclear if the Applicant has additional sensing circuitry to detect the T wave or if the T wave is sensed with the same circuitry that detects the "QRS complex".

2. Claims 1, 3, 12-13, 15-17, 19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 1 and 22, it is unclear what element is measuring "the elapsed time". It is also unclear what has a "frequency bandwidth" being adjusted.

As to claim 12, it is unclear what element possess the "a high pole frequency" since it is not positively recited in claim 12.

As to claims 3, 12-13, 15-17 and 19, Claim 3 recites the limitation, "by the therapy event and evoked and intrinsic". It is unclear if all three of these signals or at least one of the three.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-7, 11-23, 39-41 and 43-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stotts et al. (US 5,161,529). Stotts et al. discloses a pacemaker that “allows switching of the amplifier's bandpass frequency characteristic thereby selectively varying the cardiac signal frequencies subject to sensing” (abstract).

“The sense amplifier comprises a switched capacitor amplifier which allows the amplifier's bandpass frequency to be switched at will, thereby selectively varying the cardiac signal frequencies subjected to sensing. The effect is to provide a sense amplifier with a programmable frequency response” (col. 3, lines 8-11).

“Prior to the application of a pacing stimulus to the heart, the frequency response (bandpass characteristic) of the sense amplifier is selectively set to detect cardiac activity in the form of the intrinsic QRS pattern, in the same manner as is customary with pacemakers of the prior art. However, at the moment that a stimulating pulse is delivered to the heart, the sense amplifier is switched to a lower frequency bandpass to render it more responsive to an evoked potential (for example, the T wave). After a time interval during which an evoked response to the stimulus should have been detected (the presence or absence of such a response being indicative of capture or the lack of capture, respectively), the amplifier is switched back to the original bandpass characteristic to sense the intrinsic response”(col. 3, lines 14-28).

Furthermore, “the complete sense amplifier is a cascade of highpass and lowpass stages which produces a bandpass characteristic which has frequency

programmability together with switching the sense amplifier to a higher gain setting, which is suitable to sense potentials evoked by the stimulus”(col. 4, lines 60-65).

As to claims 1 and 22, Stotts et al. discloses the modification of the frequency band in the sensing circuit, but is silent whether this change is gradual between the switching. However, the examiner considers the adjustments between the frequency bands to be “gradual adjustment” since the adjustments in the frequency bands are measured and not extreme or drastic.

In the alternative, although the examiner considers Stotts et al. to disclose a gradual adjustment of the frequency bands above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make gradual adjustments to the frequency bandwidth in order to provide the predictable results of providing a smoother transition between frequency bandwidths and ensuring that signals that might exist between the transition period between the frequency bands can be detected.

As to claims 40-41 and 44-45, the first time period is by a therapy event, such as a stimulation pulse to elicit an evoked response. Thus the examiner considers the first time period to be initialed by the therapy event and the evoked event of the heart signal.

2. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stotts et al. (US 5,161,529). Stotts et al. discloses the claimed invention except for the range of time for the first time period. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the range of time for the first time period, since it has been held that where the general conditions of a claim are

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disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). Furthermore, a modification to the range of time of the first time period would provide the predictable results of modifying the treatment to meet specific patient needs.

As to claims 42 and 46, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the initiation of the first time period in order to provide the predictable result of enabling the medical device to monitor the intrinsic cardiac event prior to the therapy event in order to determine cardiac wellbeing. Furthermore, such a modification would provide the predictable results of modifying treatment to meet specific patient needs and requirements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762